DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 5, 2014

John Neacsu
Business Owner
Pro Dental Services, LLC
1121 Player Way
Herndon, VA 20170

Re: K132245
Trade/Device Name: AJAX dental unit
Regulation Number: 21 CFR 872. 6640
Regulation Name: Dental Unit with Chair
Regulatory Class: I
Product Code: EIA
Dated: May 1, 2014
Received: August 6, 2014

Dear Mr. Neacsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132245

Device Name: Dental Unit With Chair Model AJ1X

Indications For Use:

The dental chair is used so that the patient at the dentist office may sit on it while the dentist is performing diagnosis, treatment, and/or operation. The dental unit consists of patient chair, dentist element, assistant element, water unit, arm system, cuspidor unit, and dental light. The Dental Unit with Chair is intended to supply power to and serve as a base for dental devices and accessories. It is intended for use in the dental clinic/office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.

Prescription Use _____X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

(per CFR 807.92(c))

Submission Date: Dec 09, 2013

Submission Correspondent:

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USA
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Contact: John Neacsu
Business Owner

Sponsor and Manufacturer:

Guangzhou Ajax Medical Equipment
No. 80 Zhujiang Road
Shilou Town
Panyu District
Guangzhou, China
Phone: 086-20-8484-7938
Email: ajax@ajaxdent.com
Contact: Kent Zhao

Device trade name: Ajax Dental Unit – AJ1X

Common name: Dental Unit with Chair

Device classification name: EIA, Dental operative unit and accessories, 21 CFR 872.6640

Legally marketed device to which device is substantially equivalent:

1. A-DEC 200 Dental System, K102234, Manufactured by A-DEC, Inc.
2. Dental Unit with Chair, K080438, Manufactured by North West Medical Instrument (Group) Co., Ltd.

Description of device: Ajax Dental Unit AJ1X is a dental operative unit attached to a chair. It consists of a patient chair, dentist element, assistant element, water unit, arm system, cuspidor unit, and dental light. The AJ1X unit is specially designed to meet the needs of dental professionals. The concept of hygienic treatment is emphasized in the unit design. Components are designed in the way which dentist can easily maintain and clean. Concept of the unit is to optimize the work for dental practice, as well as provide a very clean and healthy treatment environment for both dentists and patients.

Intended use of device: The dental chair is used so that the patient at the dentist office may sit on it while the dentist is performing diagnosis, treatment, and/or operation. The dental unit consists of patient chair, dentist element, assistant element, water unit, arm system, cuspidor unit, and dental light. The Dental Unit with Chair is intended to supply power to and serve as a base for dental devices and accessories. It is intended for use in the dental clinic/office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.

Technological characteristics: The technological characteristics between the predicate and proposed device are similar. Both are chair mounted dental units which supply power and serve as a base for dental devices and accessories.

Non clinical testing:

- IEC 60601-1-2 Test for Medical Electrical Equipment was performed on 04/13/2012 for General requirements for basic safety and essential performance (collateral standard: electromagnetic compatibility) with the following outcome: complied with standards.

- IEC 60601-1 Test for Medical Electrical Equipment was performed on 04/30/2012 for General Requirements for basic safety and essential performance with the following outcome: fulfilled the requirements of specified standards, was subjected to full test.

- ISO7494-2 Test was performed on 04/18/2012 for requirements for water and air supply with the following outcome: pass.

- ISO7494-1 Test was performed for General requirements and test methods with the following outcome: pass.

- ISO9168 Test was performed on 04/25/2012 for Hose connectors for air driven dental hand pieces with the following outcome: pass.

- ISO6875 Test was performed on 04/20/2012 for General, electrical, and mechanical requirements with the following outcome: pass.

Conclusions: There are no significant differences between the Ajax Dental Unit AJ1X and the predicate devices, therefore, the proposed device does not raise any questions regarding safety and effectiveness.

The Ajax Dental Unit AJ1X, as designed, is as safe and effective as the predicate device. Comparisons have been made to a legally marketed predicate device, and the device is determined to be substantially equivalent to the referenced predicate device currently on the market.